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19. ABSTRACT (Continue on reverse if necessary and identify by block number) The timely and efficient execution of the U.S. Army Medical Materiel Pharmaceutical Development Program requires a thorough knowledge of regulations issued by the U.S. Food and Drug Administration. In order to accomplish the execution of this drug development program, the Pharmaceutical System Project Management Office, an element of the U.S. Army Medical Materiel Development Activity (USAMMDA), awarded a multi-year contract to Engineering and Economics Research (ORIC). The EER/ORIC team has provided the necessary managerial and technical expertise to complete the preparation and assembly of IND/NDAs. A total of six modifications to existing tasks were submitted to the contractor during the fourth contract year. For the duration of the contract, 18 task orders and 21 task order modifications were submitted to the contractor. All task orders were completed or are in progress within the project delivery schedule and cost estimate.					
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DRUG REGULATORY AFFAIRS

ANNUAL FINAL REPORT

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Supported by

U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND  
Fort Detrick, Frederick, Maryland 21701-5012

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authorized documents

FOREWORD

For the protection of human subjects the investigator(s) have adhered to policies of applicable Federal Law 45CFR46.



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## TABLE OF CONTENTS

	Page
Foreword . . . . .	i
1.0 Introduction . . . . .	1
2.0 Discussion . . . . .	2
Task 86-01 . . . . .	2
Task 86-02 . . . . .	3
Task 86-03 . . . . .	9
Task 86-04 . . . . .	10
Task 87-01 . . . . .	10
Task 87-02 . . . . .	11
Task 87-03 . . . . .	11
Task 87-04 . . . . .	11
Task 87-05 . . . . .	12
Task 87-06 . . . . .	12
Task 87-07 . . . . .	13
Task 87-08 . . . . .	13
Task 87-09 . . . . .	13
Task 88-12 . . . . .	14
Task 88-13 . . . . .	14
Task 88-14 . . . . .	14
Task 89-15 . . . . .	14
3.0 Status of Accomplishments . . . . .	15
4.0 Annual Financial Report . . . . .	19
5.0 Summary and Conclusion . . . . .	25
Distribution List . . . . .	26

## 1.0

### Introduction

The Pharmaceutical Systems Project Management Division (PSPMO), an element of the U.S. Army Medical Materiel Development Activity (USAMMDA), is responsible for planning, organizing, directing, and controlling all aspects of drug development. Every stage of drug development must be in compliance with current FDA requirements. The principal objective of this contract is to prepare and assemble drug-specific, FDA-related documentation as well as a data management system to track the status of regulatory documentation. The contractor has furnished the necessary personnel, facilities, equipment, and supplies to complete the scope of work as prescribed in each task order. In accordance with Section F of the Drug Regulatory Affairs contract, quarterly reports describing the technical progress and financial status of each Task Order have been submitted. This fourth and final Annual Report describes the work performed by the contractor during the 10-month period of 01 July 1989 to 30 April 1990.

## 2.0 Discussion

### 2.1 Task 86-01 Project Planning, Coordination, and Integration

Task 86-01 requires the development and maintenance of a planning, coordinating, and task integration infrastructure for the Drug Regulatory Affairs Contract. This infrastructure provides for overall project planning and tracking, individual task planning, monthly project review meetings, monthly update reports, quarterly progress reports, and attendance at relevant professional meetings and symposia.

#### 2.1.1 Overall Project Planning and Tracking

EER has developed a cost and schedule tracking system to assist in the preparation of monthly, quarterly, and annual reports. An inventory control system to account for property purchased under the subject contract, but for which the Government retains property, has been implemented.

A central filing system has been established for all DRA-related documents. The file is maintained in the DRA library.

#### 2.1.2 Individual Task Planning

No new task orders were received from USAMMDA during this contract term. Six modifications to the existing task orders were approved. The individual task orders

and dates on which the contracting officer approved these task order modifications are summarized as follows:

<u>Task Order</u>	<u>Date Task Order Approved</u>
Task 86-02, Modification 6	21 November 1989
Task 86-03, Modification 6	27 September 1989
Modification 7	11 November 1989
Task 88-13 Modification 1	24 July 1989
Modification 2	29 November 1989
Task 89-15 Modification 1	27 July 1989

### 2.1.3

#### Overall Task Planning

The following individual task orders and task order modifications were approved by USAMMDA and sent to the contractor for the duration of subject contract (1986 to 1990):

<u>Contract Year</u>	<u>New Task Orders</u>	<u>Task Order Modifications</u>
Year 1 (02 June 1986-30 June 1987)	9	4
Year 2 (01 July 1987-30 June 1988)	5	2
Year 3 (01 July 1988-30 June 1989)	4	9
Year 4 (01 July 1989-30 April 1990)	0	6

### 2.2

#### Task 86-02 Preparation of Annual IND Progress Reports

This task requires the preparation of annual progress reports on outstanding IND submissions. Twelve INDs require the preparation of an annual report. Assessment reports were prepared prior to the

preparation of the annual report to identify outstanding documentation necessary for the completion of the report.

Upon receipt of requested documentation from USAMMDA, the contractor prepared the Annual Report.

Anniversary dates for FDA receipt of new annual reports and date last annual report was prepared are described in the following table.

<u>IND No.</u>	<u>Product</u>	<u>Category</u>	<u>Anniversary Date</u>	<u>Date of Last Submission</u>
8,990	Mefloquine (WR 142,490)	Antimalarial	23 Jun 1972	27 April 1990
9,847	Halofantrine (WR 171,669)	Antimalarial	06 Jun 1973	01 April 1989
14,150	Pentostam (WR 229,870)	Antileishmanial	01 Feb 1978	07 March 1990
16,666	Ribavirin	Antiviral	27 Jul 1979	14 Nov 1989
21,084	WR 6,026	Antileishmanial	03 Nov 1982	23 Oct 1989
23,509	Pyridostigmine (WR 270,710)	Antidote	30 Jan 1984	13 April 1990
26,740	Ketoconazole	Antileishmanial	11 Jul 1985	01 April 1989
27,503	Atropine sulfate	Antidote	20 Nov 1985	20 Dec 1989
28,301	Atropine+2PAM	Antidote	29 Apr 1986	06 April 1990
30,726	Ketoconazole vs Pentostam	Antileishmanial	29 Sep 1987	28 July 1989
30,899	Pyridostigmine sust'd release	Antidote	07 Dec 1987	22 Dec 1989
33,272	Niclosamide	Antischistosomal	01 June 1989	----New----



2.2.1      Task 86-02, Modification #1

This Task Order requires an evaluation of all existing data, information, and other pertinent material relating to oral pyridostigmine (IND 23,509).

2.2.2      Task 86-02, Modification #2

This Task Order, consisting of 10 subtasks, requires the collection and evaluation of data and preparation of annual IND progress reports.

2.2.2.1    Ketoconazole

This subtask requires the preparation of an assessment report and an annual IND progress report for ketoconazole (IND 26,740; WR 248,310). An annual report for 1989 was submitted to USAMMDA on 01 April 1989.

Status of Subtask: Complete.

2.2.2.2    Phosphorothioic Acid

This subtask requires the duplication and filing of Supplement #9 in the DRA library (IND 5,509; WR 2,721). IND inactivated.

Status of Subtask: Complete.

2.2.2.3    Phosphorothioate

IND inactivated.

Status of subtask: Complete.

#### 2.2.2.4 Mefloquine

NDA approved on 02 May 1989 (NDA 19-578).

An Annual IND Progress Report for 1989 was submitted to USAMMDA on 05 October 1989. This subtask requires the analysis of 4 clinical studies consisting of 506 patients; the preparation of 4 clinical summary reports; and submission of these reports to the FDA as Clinical Information Reports (IND 8,990; WR 142,490).

- o Study No. 1 (Comparative treatment of 162 patients treated with Enpiroline or Mefloquine)
- o Study No. 2 (Mefloquine pharmacokinetic study of 39 patients)
- o Study No. 3 (Comparative treatment of 80 patients treated with mefloquine, quinine and tetracycline or quinine and doxycycline)
- o Study No., 4 (Comparative treatment of 225 patients treated with quinine or mefloquine)

Status of Subtask: Complete.

#### 2.2.2.5 Halofantrine

This subtask requires the preparation of a clinical information report based upon receipt of a bioavailability report from WRAIR. An annual IND progress report for 1989 was submitted to USAMMDA on 26 April 1989 (IND 9,847; WR 171,669).

Status: Complete.

2.2.2.6      Enpiroline

This subtask required the preparation of an annual IND progress report for IND 12,735; WR 180,409. IND inactivated.

Status: Complete.

2.2.2.7      WR 6,026

This subtask requires the analysis of a pharmacokinetic study and preparation of an annual IND progress report (IND 21,084). An IND annual progress report for 1989 was submitted on 23 January 1989.

Status: Complete.

2.2.2.8      Pentostam

This subtask requires the collection, duplication, and analysis of clinical data from 43 patients as well as the preparation of an annual IND progress report (IND 14,150; WR 229,870). An IND annual progress report for 1989 was submitted to USAMMDA on 07 March 1990.

Status: Complete.

2.2.2.9      Temefos

This subtask required the preparation of an annual IND progress report for IND 14,252. IND inactivated.

Status: Complete.

2.2.2.10     Atropine Sulfate, USP

This subtask requires the preparation of an annual IND progress report (IND 27,503). An IND annual progress

report for 1989 was submitted on 20 December 1989.  
Status: Complete.

2.2.2.11 Atropine 2-PAM

This subtask requires the preparation of an annual IND progress report (IND 28,301). A final IND annual progress report for 1989 was submitted to USAMMDA on 06 April 1990.  
Status: Complete.

2.2.2.12 Ketoconazole vs. Pentostam

This subtask requires the preparation of an annual IND progress report (IND 30,726). An IND annual progress report was submitted to USAMMDA on 28 July 1989.  
Status: Complete.

2.3 Task 86-02 Preparation of Information Amendments

This task requires the preparation of information amendments to active IND applications. The following table describes the preparation of these reports:

<u>IND NO.</u>	<u>Product</u>	<u>Category</u>	<u>Type of Amendment</u>	<u>Date of Submission</u>
8,990	Mefloquine (WR 142,490)	Antimalarial	Clinical	23 Feb 1990
			Clinical	03 April 1990
			Clinical	30 April 1990
			Clinical	30 April 1990
16,666	Ribavirin	Antiviral	Clinical	30 March 1990
23,509	Pyridostigmine	Antidote	Clinical	13 Nov 1989
30,899	Pyridostigmine Sust'd Release	Antidote	Manufacturing	22 Dec 1989

## 2.4 Task 86-03 Preparation of an NDA for Ribavirin

This task requires the collection and analysis of preclinical and clinical information for the parenteral formulation of ribavirin, as well as the preparation and submission of an NDA in the format required by 21 CFR 314.50. In conjunction with the NDA preparation, data collection and analysis were performed at Viratek (Modification No. 4) and Centers for Disease Control (Modification No. 5). Additional data analysis support for USAMRIID was provided (Modification Nos. 6 and 7.)

### 2.4.1 Ribavirin NDA Team Meetings

NDA team meetings were held with USAMMDA, USAMRIID staff and Oxford Research on 17 and 18 September as well as 5 October to discuss additional statistical analysis support for the EHFRS clinical section of the NDA.

### 2.4.2 NDA Documentation

A working draft report of the toxicology and metabolism sections was submitted to USAMMDA on 20 December 1988.

A working draft report of the antiviral human pharmacokinetics and bioavailability was submitted to USAMMDA on 23 December 1988.

A working draft report of the clinical section was submitted to USAMMDA on 16 January 1989.

Status: In progress.

2.5      Task 86-04 Data Management for Document Presentation

New documents continue to be added to the regulatory library and its associated data base management system. Total records number 750 and require over one megabyte of disk storage space.

A duplicate data base management system is maintained at USAMMMDA, which is updated periodically with information and program updates transferred via DC 1000 20 megabyte magnetic tape. A tape is sent every 2 months with a hard copy catalog of library documents, sorted by IND number.

Two additional management reports have been added to the system, the "IND/NDA Document Category Summary" and the "Annual Report Preparation Summary."  
Status of Task: Complete.

2.6      Task 87-01 Halofantrine

The purpose of this task was to determine whether there was adequate data to support an NDA for Halofantrine. This drug is being studied for use in the prophylaxis and treatment of malaria caused by P. falciparum. This report identified both the strengths and weaknesses of the manufacturing and

control, pre-clinical, and clinical sections of the NDA.

Status of Task: Complete.

2.7      Task 87-02 Literature Review of Cholinergic Inhibitors

This task required the preparation of a literature review on the toxicology resulting from inhibition of acetylcholinesterase on the neuromuscular junction. This review was written for inclusion in Section 6 of the IND. An executive summary of the literature was also prepared for review by a Pyridostigmine Blue Ribbon Committee.

Status of Task: Complete.

2.8      Task 87-03 Pharmacokinetic Analysis of Atropine

The purpose of this task was to prepare a scientific report for the study: "A Comparative Analysis of the Pharmacokinetic Properties of Intramuscularly-Administered Atropine in Humans and Rhesus Monkeys."

Status of Task: Complete.

2.9      Task 87-04 Pyridostigmine Pharmacokinetic Analysis

The requirements of this task included (1) summarization of data on cholinesterase inhibition with descriptive statistics for time and dose and (2) preparation of a pharmacokinetic report on plasma pyridostigmine levels and a correlation analysis of cholinesterase inhibition and associated plasma pyridostigmine levels.

A comparative bioavailability cross-over design study of 18 subjects carried out at a dose level of 30 mg confirmed no significant difference between the tablet and syrup formulation of pyridostigmine.

Status of Task: Complete.

2.10

Task 87-05 Pyridostigmine Acetylcholinesterase Statistical Study

This task required the analysis of a pharmacokinetic study conducted in Rhesus monkeys and man to determine the dose effect relationship of pyridostigmine and inhibition of acetylcholinesterase between the two species. The results from this study will be used to support the hypothesis that extrapolation of monkey data to man is valid.

The pyridostigmine plasma AUC is greater in man as compared to monkey. The AUC response for both species was shown to be dose dependent and linear for dose. However, a non-linear relationship was observed with respect to RBC acetylcholinesterase inhibition and pyridostigmine dose. These results appear to indicate that higher doses of pyridostigmine probably would not result in a linear increase in acetylcholinesterase inhibition.

Status of Task: Complete.

2.11

Task 87-06 IND Preparation for Pentostam-Ketoconazole

This task required the preparation of a "Notice of Claimed Investigational Exemption for a New Drug" (IND) in accordance with 21 CFR 312.10 (old format).



The application has been approved by FDA and assigned  
IND No. 30,726.

Status of Task: Complete.

2.12      Task 87-07 Technical Support for Army  
Pharmaceutical Advisory Committee Meeting

This task required scientific and regulatory review of  
cumulative IND summaries of five drugs. The specified  
documents were photocopied and collated for  
presentation to the Army Pharmaceutical Advisory  
Committee (WRAIR).

Status of Task: Complete.

2.13      Task 87-08 IND Preparation for the Oral  
Sustained Release Formulation of  
Pyridostigmine

This task required the preparation of a "Notice of  
Claimed Investigational Exemption for a New Drug"  
(IND) in accordance with 21 CFR 312.10 (old format).  
This application has been approved and assigned IND  
No. 30,899.

Status of Task: Complete .

2.14      Task 87-09 Pyridostigmine, Amendment to  
Clinical Section

This task required the preparation of an Amendment to  
the Clinical Section of IND No. 23,509 by providing  
analysis of the investigation conducted by Allstatt  
and subsequent comments by Dr. Edward Purich.

Status of Task: Complete.

2.15      Task 88-12   IND Preparation for  
Schistosome Topical Antipenetrant

This task required the preparation of a "Notice of Claimed Investigational Exemption for a New Drug" and clinical protocol. The application has been approved by FDA and assigned IND No. 33,272.  
Status of Task:   Complete.

2.16      Task 88-13   Permethrin

This task required the preparation of an EPA registration package. The final EPA registration package was submitted to USAMMDA on 18 January 1990.  
Status of Task:   Complete.

2.17      Task 88-14   Mefloquine-Enpiroline Evaluation

This task required the preparation of a scientific report on available data on mefloquine and enpiroline for future scientific and regulatory action. The final report was submitted to USAMMDA on 24 July 1989.  
Status of Task:   Complete.

2.18      Task 89-15   Preparation of Nonclinical Section for  
Hypertonic Saline with Dextran

This task required the preparation of a nonclinical section based on data obtained from LAIR. This section was used to support an NDA sponsored by Pharmacia AB. The non-clinical section was submitted to Pharmacia on 19 April 1990.  
Status of Task:   Complete.

3.0

Status of Accomplishments

A total of six modifications to existing tasks were submitted to the contractor during this performance period. All tasks/subtasks are complete. The following table summarizes the technical progress for each task/subtask.

SUMMARY TABLE  
TASK ORDER TECHNICAL PROGRESS

<u>Task Order</u>	<u>Deliverable</u>	<u>Submission Date</u>	<u>Status of Task Order</u>	<u>Status of Subtask</u>
86-01	Quarterly Report #9	10/15/88	complete	complete
	Quarterly Report #10	01/15/89		complete
	Quarterly Report #11	04/15/89		complete
	Quarterly Report #12	07/15/89		complete
	Annual Report	07/15/89		complete
	Monthly Reports	08/01/88 - 03/01/90		complete
86-02	Pyridostigmine		complete	
	IND Annual Report*	04/12/90		complete
	Ketoconazole			
	IND Annual Report	04/01/90		complete
	Mefloquine			
	Amendment Reports			
	Study No. 1	12/23/90		complete
	Study No. 2	04/30/90		complete
	Study No. 3	04/03/90		complete
	Study No. 4	04/30/90		complete
	IND Annual Report	10/05/89		complete
	Halofantrine			
	IND Annual Report	04/01/89		complete
	Antileishmanial (WR 6,026)			
	IND Annual Report	10/23/89		complete
	Pentostam			
	IND Annual Report	03/07/90		complete
	Atropine Sulfate, USP			
	IND Annual Report	12/20/88		complete
	Atropine-2PAM			
	IND Annual Report	03/22/90		complete
	Pyridostigmine Sustained Release			
	IND Annual Report	12/22/89		complete
	Ketoconazole-Pentostam			
	IND Annual Report	07/28/89		complete
	Ribavirin			
	IND Annual Report	11/14/89		complete

\*draft report

<u>Task Order</u>	<u>Deliverable</u>	<u>Submission Date</u>	<u>Status of Task Order</u>	<u>Status of Subtask</u>
86-03	Ribavirin			
	NDA Preparation			
	Mfg. and Control Section	04/01/87	complete	
	Pre-Clinical		gov't review	
	Draft Section	12/20/88		
	Final Section			
	Clinical		gov't review	
	Draft Section	01/16/89		
	Final Section			
86-04	Document Management		complete	
	Tape Cartridge Delivery	07/07/88		
		10/06/88		
		01/03/90		
		03/22/90		
87-01	Halofantrine	03/23/87	complete	
	NDA Evaluation			
87-02	Acetylcholinesterase		complete	
	Literature Review			
87-03	Atropine Pharmacokinetic		complete	
	Analysis			
87-04	Pyridostigmine Pharmacokinetic		complete	
	Analysis			
	Draft Clinical Report	03/27/87		
	Final Clinical Report	02/13/89		
87-05	Pyridostigmine-		complete	
	Acetylcholinesterase			
	Statistical Study			
	Draft Clinical Report	06/26/87		
	Final Clinical Report	02/13/89		
87-06	IND Preparation for		complete	
	Pentostam-Ketoconazole			
	Draft IND	10/02/87	complete	
	Final IND	10/02/87	complete	
87-07	WRAIR Pharmaceutical			
	Advisory Committee Support	10/09/87	complete	

<u>Task Order</u>	<u>Deliverable</u>	<u>Submission Date</u>	<u>Status of Task Order</u>	<u>Status of Subtask</u>
87-08	IND Preparation for Sustained Release Pyridostigmine		complete	
	Draft IND	11/20/87		
	Final IND	11/20/87		
87-09	Pyridostigmine Clinical Report		complete	
	Draft Clinical Amendment Report	03/02/88		
	Final Clinical Amendment Report	06/28/88		
88-12	IND Preparation for Niclosamide			
	Draft IND	05/25/89	complete	
	Final IND	05/25/89		
88-13	EPA Registration for Permethrin		complete	
	Draft EPA Package	12/08/89		
	Final EPA Package	01/16/90		
88-14	Mefloquine-Enpiroline Evaluation		complete	
	Draft Report	07/20/89		
	Final Report	07/24/89		
89-15	Hypertonic Saline with Dextran Non Clinical Report		complete	
	Draft Report	01/05/90		
	Final Report	04/20/89		

## AMR - PLANNED COST SCHEDULE

DATE TASK APPROVED BY CO	TASK NO.	DOLLAR AMOUNT APPROVED WITH FEE	TOTAL CUMULATIVE AMOUNT WITH FEE	START DATE	STOP DATE	DURATION
07/02/86	8601	\$375,973	\$ 375,973	06/02/86	07/31/88	26 months
07/08/86	8602	\$ 62,714	\$ 438,687	06/18/86	07/31/88	26 months
07/18/86	8603	\$180,343	\$ 619,030	07/01/86	05/01/87	10 months
08/26/86	8604	\$ 88,628	\$ 707,658	07/01/86	07/31/88	24 months
10/20/86	8701	\$ 59,887	\$ 767,545	10/28/86	03/31/87	5 months
11/04/86	8702	\$ 18,328	\$ 785,873	10/20/86	01/30/87	3 months
12/04/86	8703	\$ 28,496	\$ 814,369	10/27/86	02/28/87	4 months
12/04/86	8704	\$ 21,190	\$ 835,559	10/27/86	02/28/87	4 months
02/25/87	8704 (MOD 1)	\$ 4,823	\$ 840,382	10/27/86 (02/25/87)	04/30/87	2 months
03/26/87	8705	\$ 23,638	\$ 864,020	02/12/87	04/30/87	3 months
04/07/87	8602 (MOD 2)	\$172,711	\$1,036,731	02/11/87 (04/07/87)	12/31/87	9 months
05/29/87	8601 (MOD 1)	\$ 7,054	\$1,043,785	06/02/87	07/01/88	13 months
06/11/87	8603 (MOD 1)	\$ 23,812	\$1,067,597	07/01/87	09/30/87	3 months

( ) Effective Date of Modification

AMR - PLANNED COST SCHEDULE

DATE TASK APPROVED BY CO	TASK NO.	DOLLAR AMOUNT APPROVED WITH FEE	TOTAL CUMULATIVE AMOUNT WITH FEE	START DATE	STOP DATE	DURATION
07/08/87	8705 (MOD 1)	\$ 7,069	\$1,074,666	07/08/89	09/30/87	3 months
09/21/87	8706	\$ 46,125	\$1,120,791	08/25/87	12/31/87	4 months
10/07/87	8707	\$ 5,467	\$1,126,258	09/15/87	11/30/87	3 months
10/23/87	8708	\$ 35,567	\$1,161,825	09/25/98	12/31/87	3 months
01/22/88	8709	\$ 12,160	\$1,173,985	11/09/87	02/08/88	3 months
03/03/88	8602 (MOD 3)	\$ 60,547	\$1,234,532	03/03/88	07/01/88	4 months
04/28/88	8812	\$ 35,515	\$1,270,047	04/20/88	12/30/88	8 months
07/08/88	8603 (MOD 2)	\$ 62,486	\$1,332,533	04/15/88	04/15/89	12 months
07/08/88	8604 (MOD 1)	\$ 41,452	\$1,373,985	06/02/88	06/01/89	12 months
07/08/88	8602 (MOD 5)	\$ 40,827	\$1,414,812	07/01/88	06/30/89	12 months
08/15/88	8601 (MOD 2)	\$187,201	\$1,602,013	07/01/88	06/30/89	12 months
09/30/88	8813	\$ 52,112	\$1,654,125	08/31/88	09/30/89	13 months
10/04/88	8603 (MOD 3)	\$ 13,793	\$1,667,918	10/01/88	11/15/88	2 months
12/19/88	8603 (MOD 4)	\$ 32,725	\$1,700,643	12/15/88	06/30/89	6 months
01/27/89	8814	\$ 10,106	\$1,710,749	02/01/89	05/30/89	4 months



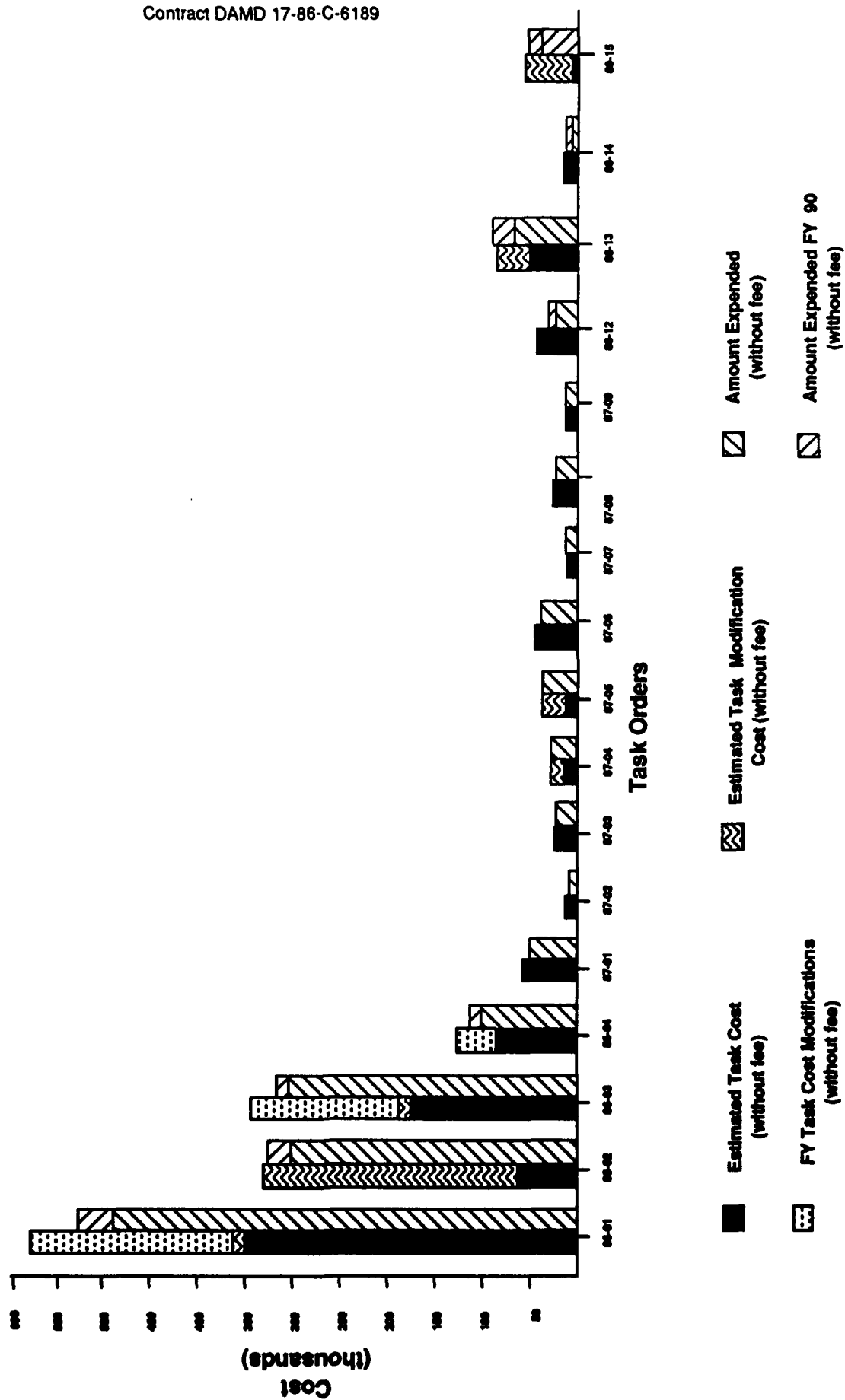
AMR - PLANNED COST SCHEDULE

DATE TASK APPROVED BY CO	TASK NO.	DOLLAR AMOUNT APPROVED WITH FEE	TOTAL CUMULATIVE AMOUNT WITH FEE	START DATE	STOP DATE	DURATION
05/18/89	8603 (MOD 5)	\$ 20,083	\$1,730,832	06/15/89	09/30/89	3 months
06/14/89	8604 (MOD 2)	\$ 15,159	\$1,745,991	07/01/89	10/31/89	4 months
06/18/89	8601 (MOD 3)	\$ 48,558	\$1,794,549	06/02/89	10/31/89	5 months
07/24/89	8813 (MOD 1)	\$ 22,382	\$1,816,931	06/20/89	10/15/89	5 months
09/07/89	8603 (MOD 6)	\$ 13,094	\$1,830,025	09/07/89	11/01/89	3 months
07/03/89	8915	\$ 6,624	\$1,836,649	07/01/89	10/30/89	4 months
07/27/89	8915 (MOD 1)	\$ 32,930	\$1,869,579	07/12/89	12/30/89	6 months
11/21/89	8602 (MOD 6)	\$ 19,534	\$1,889,113	09/30/89	01/31/90	4 months
11/21/89	8603 (MOD 7)	\$ 19,514	\$1,908,627	10/01/89	12/31/89	3 months
11/27/89	8813 (MOD 2)	\$ 11,861	\$1,920,488	06/20/89	12/31/89	7 months

# Estimated vs Expended

Drug Regulatory Affairs Contract  
as of 03/16/90

30 June 1989 - 16 March 1990  
Contract DAMD 17-86-C-6189



Financial Information<sup>1</sup>  
DAMD17-86-C-6189  
as of 03/16/90

<u>Task No.</u>	<u>Funds Negotiated</u>	<u>Cost Incurred</u>	<u>\$ Expended (%)</u>
8601	\$576,154	525,199	91.2
8602	333,596	332,986	99.8
8603	349,181	317,682	91.0
8604	133,246	122,867	92.2
8701	57,635	55,540	96.4
8702	16,815	15,822	94.1
8703	27,573	27,474	99.6
8704	24,168	24,994	103.4
8705	28,685	28,495	99.3
8706	42,316	41,464	98.0
8707	5,015	5,168	103.1
8708	32,630	26,653	81.7
8709	11,240	11,668	103.8
8811	0	cancelled	0
8812	35,515	27,902	78.6
8813	79,224	80,982	102.2
8814	9,271	8,875	95.7
8915	36,288	35,460	97.7

Total Contract  
Amount Negotiated \$1,836,576

Amount Expended  
through 03/16/90 \$1,689,231

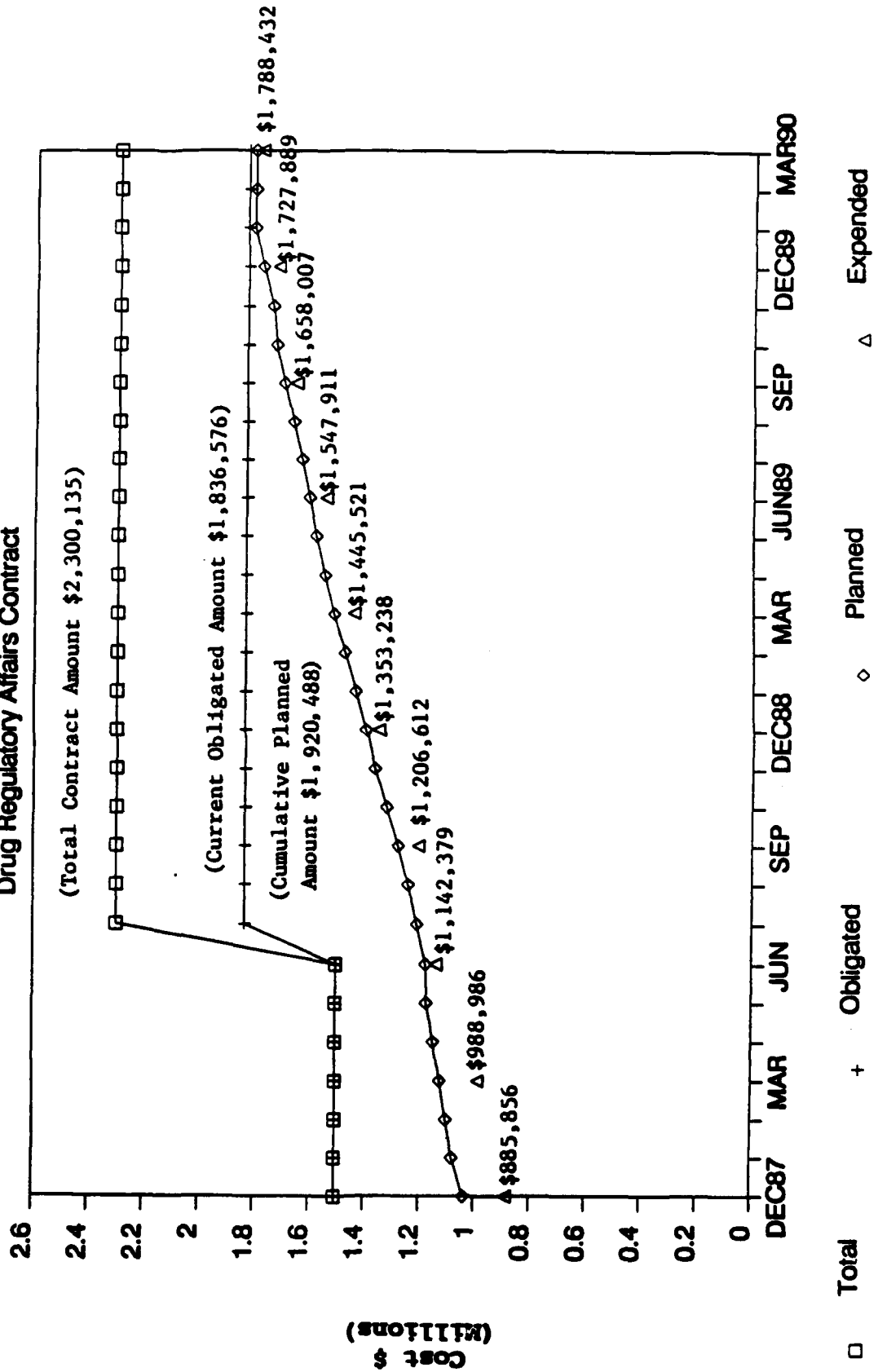
Percent of total contract amount  
negotiated expended through 03/16/90 92.0

(<sup>1</sup>) These figures do not include fee.

The total number of manhours expended to date is 35,727

# Financial Analysis

## Drug Regulatory Affairs Contract



## 5.0

### Summary and Conclusion

Continuing progress was made during the fourth year of the Drug Regulatory Affairs contract. A total of six modifications to existing tasks were submitted to the contractor during this performance period. All tasks/subtasks were completed within the projected delivery schedule and cost estimate as described in the respective Task Execution Plans.

This technical progress was achieved through cooperative interaction with the Contracting Officer's Representative, Dr. Carl Nielsen and Dr. Ronald Clawson; Colonel Robert Pick; Dr. Anna Johnson-Winegar; and other members of the Pharmaceutical Systems Project Management Division. The contractor wishes to express appreciation for the continued excellent and cooperative professional relationship.

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